IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENZO LIFE SCIENCES, INC.,	)	
	)	
Plaintiff.	)	
	)	
v.	)	C.A. No. 12-274-LPS
	)	
ABBOTT LABORATORIES and ABBOTT MOLECULAR, INC.,	)	
	)	
Defendants.	)	
	)	

Brian E. Farnan, FARNAN LLP, Wilmington, DE
John M. Desmarais, Michael P. Stadnick, Justin P.D. Wilcox, Jordan Malz, Peter C. Magic, DESMARAIS LLP, New York, NY

Attorneys for Plaintiff Enzo Life Sciences, Inc.

John C. Phillips, David A. Bilson, PHILLIPS, GOLDMAN, MCLAUGHLIN & HALL LLP, Wilmington, DE
James F. Hurst, Amanda Hollis, KIRKLAND & ELLIS LLP, Chicago, IL
Benjamin A. Lasky, Stefan M. Miller, KIRKLAND & ELLIS LLP, New York, NY
Michael A. Pearson, Jr., Jason M. Wilcox, KIRKLAND & ELLIS LLP, Washington, DC

Attorneys for Defendants Abbott Laboratories and Abbott Molecular, Inc.

MEMORANDUM OPINION

August 15, 2017
Wilmington, Delaware

STARK, U.S. District Judge:

Pending before the Court are: (i) Defendants Abbott Laboratories and Abbott Molecular Inc.'s (collectively, "Abbott" or "Defendants") Motion for Summary Judgment of Invalidity of U.S. Patent No. 8,097,405 (the "'405 patent") for Failure to Comply with the Written Description Requirement (D.I. 413 at 6-16), and (ii) Abbott's Motion for Summary Judgment of Invalidity of the '405 Patent for Nonenablement (D.I. 458). For the reasons set forth below, the Court will deny Abbott's motion with respect to written description and will grant Abbott's motion with respect to nonenablement.

I. BACKGROUND

Plaintiff Enzo Life Sciences, Inc. ("Enzo" or "Plaintiff") filed this patent infringement action against Abbott, alleging infringement of the '405 patent as well as U.S. Patent No. 6,992,180 ("the '180 patent").

The '405 patent, which is the subject of the pending motions, generally pertains to non-radioactive labeling and "relate[s] to nucleic acid[[1]] detection technology that relies upon the ability of nucleic acid (DNA or RNA) strands to hybridize – or bind together." (D.I. 430 at 7) (internal quotation marks omitted) While "the prevailing perception in the art [at the time of the invention] was that specific base moieties (the so-called 'Ward' positions) were the only possible positions for labeling," the '405 patent discloses that nucleotides "with non-radioactive labels attached to certain positions of a nucleotide – the phosphate moiety, sugar moiety, or non-Ward positions on the base moiety – could . . . be used as detectable nucleic acid probes." (D.I. 423 at

[1]"Nucleic acids (DNA or RNA) are made up of 'nucleotide[s],' each of which 'typically consists of three parts: a base, a sugar, and a phosphate.'" (D.I. 430 at 7) (quoting D.I. 431-2 Ex. 16 at 9)

5-6 (emphasis omitted); *see also* D.I. 427 at A2130)

The '405 patent was issued on January 17, 2012 and claims priority to June 23, 1982. (*See* D.I. 423 at 6) The asserted claims of the '405 patent "fall into two categories: the *in situ* hybridization claims and the liquid phase claims." (D.I. 430 at 8) The *in situ* hybridization claims – claims 63, 64, 65, 94, 103, 128, and 144 – "recite processes for counting or identifying chromosomes through 'specific hybridization' to a 'locus or loci' of a chromosome, using probes labeled at specified positions." (*Id.*) The liquid phase claims – claims 196 and 198 – "specify permissible Sigs [detectable labels] and detection methods, respectively."[2] (*Id.* at 9)

Abbott moved for summary judgment of invalidity of the '405 patent for lack of written description on May 12, 2017 (D.I. 410 at 6-16; D.I. 413 at 6-16),[3] and the parties completed briefing on July 7, 2017 (D.I. 413, 423, 448). On June 28, 2017, while summary judgment briefing was underway, the Court issued a Memorandum Opinion in a related case, *Enzo Life Sciences, Inc. v. Gen-Probe Inc.*, C.A. No. 12-104-LPS, granting a defense motion for summary

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[2]Claims 94, 103, 128, and 144 depend from independent claims 63, 64, and 65, among other claims. Claims 196 and 198 depend from independent claims 188 and 189, both of which recite the following limitations that are pertinent here:

> A process for detecting the presence of a nucleic acid of interest in a sample, comprising: providing or generating (i) a detectable non-radioactively labeled oligonucleotide or polynucleotide, . . . and (ii) a sample that may contain said nucleic acid of interest; forming in liquid phase, hybrids comprising said detectable non-radioactively labeled oligonucleotide or polynucleotide specifically hybridized with said nucleic acid of interest; and detecting hybrids non-radioactively to detect the presence of said nucleic acid of interest.

('405 patent col. 54 ll. 31-67, col. 55 ll. 1-10)

[3]D.I. 413 is an amendment to Abbott's opening brief, D.I. 410, and was filed on May 12, 2017. When citing to Abbott's opening brief, this Memorandum Opinion refers to D.I. 413, not D.I. 410.

judgment that the asserted claims of the '180 patent are invalid for nonenablement. (C.A. No. 12-104-LPS D.I. 284) ("Gen-Probe Opinion" or "GP Op.") On the same day, the Court issued an oral order in the instant case, requiring the parties to submit a joint status report discussing their respective position(s) on how the Court should proceed with respect to the summary judgment motions pending here. (D.I. 441)

In their July 10 status report, the parties agreed that the Gen-Probe Opinion invalidated all of the '180 patent claims asserted against Abbott and that all pending motions pertaining to the '180 patent were now moot. (*See* D.I. 450 at 4-5) The status report also included Abbott's request for leave to file a motion for summary judgment of invalidity of the '405 patent for nonenablement. (*See id.* at 6) In Abbott's view, good cause was established by the Gen-Probe Opinion, because "the '405 patent is related to and has essentially the same specification as the '180 patent." (*Id.* at 5)

The Court granted Abbott's request for leave. (D.I. 451) Thereafter, between July 18 and August 1, 2017, the parties submitted additional letter briefing with respect to enablement. (D.I. 459, 461, 462) The Court heard oral argument on August 8, 2017. (*See* Transcript ("Tr."))

II. LEGAL STANDARDS

A. Summary Judgment

Under Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be – or,

alternatively, is – genuinely disputed must be supported either by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). The "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;" a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating

entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial"). Thus, the "mere existence of a scintilla of evidence" in support of the nonmoving party's position is insufficient to defeat a motion for summary judgment; there must be "evidence on which the jury could reasonably find" for the nonmoving party. *Anderson*, 477 U.S. at 252.

B. Patent Validity Under 35 U.S.C. § 112

Paragraph 1 of 35 U.S.C. § 112[4] states in pertinent part:

> The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

The statute sets out separate requirements for written description and enablement. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (holding that written description and enablement requirements are separate). Nonetheless, these requirements "often rise and fall together." *Id.* at 1352.

1. Written Description

Whether a specification satisfies the written description requirement is a question of fact. *See GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 729 (Fed. Cir. 2014); *see also Alcon, Inc. v. Teva Pharms. USA, Inc.*, 664 F. Supp. 2d 443, 468 (D. Del. 2009)

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[4]The patent statute was amended in September 2011 by the America Invents Act ("AIA"). *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 300-01 (2011). The pre-AIA version of § 112 applies in this case. The post-AIA version of this portion of the statute (§ 112(a)) is identical to the pre-AIA verison.

("Satisfaction of the written description requirement is a fact-based inquiry, depending on 'the nature of the claimed invention and the knowledge of one skilled in the art at the time an invention is made and a patent application is filed.'") (quoting *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)). Despite being a question of fact, the issue of invalidity for lack of written description can be amenable to summary judgment. *See, e.g.*, *Carnegie Mellon*, 541 F.3d at 1126-28 (affirming summary judgment of invalidity for lack of written description); *see also Helicos Biosciences Corp. v. Illumina, Inc.*, 888 F. Supp. 2d 519, 530-31 (D. Del. 2012) ("While compliance with the written description requirement is a question of fact, the issue is 'amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party.'") (quoting *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008)).

To comply with the written description requirement, a patent's specification "must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad*, 598 F.3d at 1351 (internal brackets and quotation marks omitted). "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* "[T]he hallmark of written description is disclosure. Thus, 'possession as shown in the disclosure' is a more complete formulation" of the written description requirement. *Id.* "[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* "[T]he written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description

requirement." *Id.* at 1352. However, "a description that merely renders the invention obvious does not satisfy the requirement." *Id.*

2. Enablement

"Enablement is a question of law based on underlying factual findings." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Id.* (internal quotation marks omitted). "Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention." *Id.* at 1380-81. "Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage." *Id.* at 1381. "The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Id.* (internal quotation marks omitted).

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* Although "a specification need not disclose what is well known in the art," "[t]ossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech, Inc.*

v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997). A patent "cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification." *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010).

III. DISCUSSION

A. Written Description

1. Written Description for Hybridization and Detection of Probes Labeled at Non-Ward Positions

Abbott seeks summary judgment that the '405 patent contains insufficient written description for non-Ward-labeled probes used for hybridization and detection. (*See* D.I. 413 at 9) In Abbott's view, the '405 patent specification "at best describes that probes . . . labeled at non-Ward positions could be made, would hybridize to complementary nucleic acids of interest, and would be detected," but describes no such testing. (*Id.* at 11) Abbott further contends that "it would have been necessary to make and test [a non-Ward-labeled probe]" because, as of the priority date, "non-Ward labeling was believed to be disruptive and unsuitable" and the Ward patent[5] taught away from attaching a non-radioactive label to any position other than a Ward position. (*Id.* at 9, 11 (internal quotation marks omitted; alteration in original); *see also* D.I. 411-4 Ex. 21 at 63)

Enzo responds that the specification "provide[s] numerous specific examples of labeling probes at . . . non-Ward positions." (D.I. 423 at 14) Specifically, Enzo contends that Example V discloses phosphate labeling (*see* '405 patent col. 5 ll. 40-53); Example XXXIII describes base labeling at non-Ward positions (*see* '405 patent col. 4 ll. 16-24, col. 13 ll. 23-53); and the

[5]The Ward patent discloses labeling at the Ward positions of the base moiety. The '405 patent incorporates by reference the specification of the Ward patent. (*See* D.I. 413 at 7; '405 patent col. 3 ll. 15-17)

specification describes labeling at the sugar moiety (*see* '405 patent col. 3 ll. 45-53). (*See* D.I. 423 at 14-15) Enzo further contends that the specification discloses that "hybridization and detection are the plain purposes to which each of the above examples are directed." (*Id.* at 15; *see also* '405 patent col. 29 ll. 34-38) According to Enzo, a person of ordinary skill in the art ("POSA") would have "understood each of the examples discussed above to be a complete embodiment of the claimed probes" (D.I. 423 at 15 n.10) (emphasis omitted) and would have also been aware of "a variety of additional chemistries" for labeling at non-Ward positions (*id.* at 16). Thus, in Enzo's view, "[a]t a minimum, the presence of numerous specific examples of the inventions, and both sides' expert opinions regarding those examples, creates disputes of material fact," precluding summary judgment. (*Id.* at 17)

The Court agrees with Enzo that genuine disputes of material fact preclude summary judgment on whether the '405 patent contains sufficient written description for non-Ward-labeled probes used for hybridization and detection. (*See, e.g.*, D.I. 411-4 Ex. 21 at 63; D.I. 427 at A2331-55; '405 patent col. 29 ll. 34-38) A reasonable factfinder could find, as Abbott contends, that no portion of the specification discloses non-Ward-labeled probes that could successfully hybridize or be detected. (*See* D.I. 413 at 9, 11) By contrast, a reasonable factfinder could also find, as Enzo asserts, that various parts of the specification disclose non-Ward-labeled polynucleotides that are useful for hybridization and detection. (*See* D.I. 423 at 14-16)

Accordingly, the Court will deny this portion of Abbott's motion for summary judgment.

2. Written Description for the *In Situ* Hybridization Claims

Abbott seeks summary judgment that the '405 patent lacks adequate written description for the claimed processes recited in the *in situ* hybridization claims – specifically, the processes

for "determining whether the number of copies of a particular chromosome in a cell is normal or abnormal," "identifying a chromosome of interest in a cell containing other chromosomes," and "identifying a plurality or all of the chromosomes of a cell of interest." (D.I. 413 at 15; *see also* '405 patent col. 34 ll. 62-64, col. 36 ll. 1-2, col. 37 ll. 7-8) Abbott contends that "[t]he only portions of the '405 patent [that] Enzo identifies as containing any disclosure of th[ose] processes are the title and abstract," both of which were added 20 years after the priority date. (D.I. 413 at 15-16) (emphasis omitted) Abbott further contends that Example 9 of the Ward patent cannot provide adequate written description for the *in situ* hybridization claims because that Example was prophetic and could not be practiced until 1996. (*See id.* at 16; D.I. 411-4 Ex. 27 at 31-34)

Enzo counters that Example 9 provides sufficient written description for the *in situ* hybridization claims because Abbott's own expert admitted that "[c]ertain embodiments [of Example 9] certainly could be practiced without question" in 1981. (D.I. 425 at A809; *see also* D.I. 423 at 19 n.10) Enzo further contends that "*in situ* hybridization with human and non-human chromosomes was well known by 1982" and, therefore, was available to a POSA as of the priority date. (D.I. 423 at 9)

The Court concludes that the record reveals a genuine dispute of material fact with respect to whether Example 9 could be practiced before the priority date. While Abbott contends that the relevant portions of Example 9 could not be practiced until approximately 14 years after the priority date (*see* D.I. 411-4 Ex. 27 at 31-34), Enzo cites record evidence that "[c]ertain embodiments . . . certainly could be practiced without question" before the priority date (D.I. 425 at A809). A reasonable jury, viewing such evidence, could find for either Abbott or Enzo on this dispute.

Accordingly, the Court will deny this portion of Abbott's motion for summary judgment.

3. Written Description for the Liquid Phase Claims

Abbott requests that the Court grant summary judgment that the '405 patent lacks adequate written description for the liquid phase claims. In support, Abbott argues that the specification of the '405 patent "does not describe any oligo- or polynucleotide . . . used for specific hybridization in liquid phase to detect a nucleic acid of interest in a sample," as required by the liquid phase claims. (D.I. 413 at 13)

Enzo responds that the specification "explicitly describe[s]" the probes useful for "detection or hybridization in the liquid phase between the DNA sought to be detected and the DNA detecting probe." (D.I. 423 at 15 (internal quotation marks omitted); *see also* '405 patent col. 19 ll. 63-65; col. 20 ll. 1-10)) Enzo further asserts that "[h]ybridization in the liquid phase was known in the art" and, therefore, available to a POSA as of the priority date. (D.I. 423 at 9)

The record demonstrates genuine disputes of fact with respect to whether the '405 patent contains adequate written description for the liquid phase claims. A reasonable jury could find for either side, based on the record evidence. (*See, e.g.*, D.I. 411-4 Ex. 28 at 163; '405 patent col. 19 ll. 63-65, col. 20 ll. 1-10)

Accordingly, the Court will deny this portion of Abbott's motion for summary judgment.

B. Enablement

Abbott seeks summary judgment that the asserted claims of the '405 patent are invalid for nonenablement on the basis of the Court's reasoning in the Gen-Probe Opinion. (*See* GP Op.) (granting summary judgment that asserted claims of '180 patent are invalid for nonenablement) In Abbott's view, the Court's reasoning in the Gen-Probe Opinion supports invalidating the '405

patent on enablement grounds because "[a] specification[6] that does not enable the narrower scope of polynucleotides claimed in the '180 patent cannot enable the broader scope of polynucleotides recited in the '405 patent." (D.I. 459 at 1; *see also* Tr. at 6-7, 17) Abbott further contends that the claims of the '405 patent, like those of the '180 patent, "do not limit the length or sequence of the polynucleotides and, thus, cover [the] use of at least the same millions (or more) phosphate-labeled polynucleotides that were not enabled in the '180 patent." (D.I. 459 at 1) (internal quotation marks omitted)

With respect to other polynucleotides labeled at non-Ward positions, Abbott asserts that Enzo "cannot identify any Example [in the '405 patent's specification] that describes [the] chemistry for the vast majority of the other non-Ward labeling positions that the '405 patent seeks to capture," including the chemistry for all non-Ward base labeling positions. (*Id.* at 2) Abbott further argues that the methods disclosed in the asserted claims are not enabled because Enzo's expert, Dr. Sherman, admitted that "there [is] no data in the '405 patent showing that a probe labeled at a non-Ward position . . . would successfully hybridize." (D.I. 459-1 Ex. 6 at 193-94) According to Abbott, the lack of any such experiment being reported in the specification establishes that a POSA would have had to engage in "undue experimentation" in order to confirm that non-Ward-labeled probes work, given the "vast number of possible variants to the claimed invention." (D.I. 459 at 2) (internal quotation marks omitted)

Enzo responds that "the '405 [p]atent specification describes in great detail a wide variety of non-radioactively[-]labeled polynucleotides that can be used in the claimed methods, including probes labeled . . . at . . . non-Ward positions." (D.I. 461 at 3) (citing '405 patent col. 3 ll. 20-67,

[6]It is undisputed that the specifications of the '405 patent and '180 patent are identical in relevant part. (*See* Tr. at 6)

col. 4 ll. 1-24, col. 5 ll. 40-53, col. 12 ll. 48-67, col. 13 ll. 1-54, col. 22 ll. 56-67, cols. 23-24, col. 25 ll. 1-66 as disclosing probes labeled at sugar, phosphate, and certain base moieties) Enzo further contends that "skilled artisans were aware of additional chemistries for attaching labels at the other non-Ward positions" that are not explicitly disclosed in the specification. (*Id.*) In Enzo's view, the variations in "polynucleotide sequence, length, labels, linkers, and position of labeling" would not "render any application of the claimed methods inoperable" and, therefore, a POSA could practice the invention "without engaging in undue (if any) experimentation." (*Id.* at 2-3) (emphasis omitted)

According to Enzo, the specific limitations recited in the asserted claims are adequately described in the specification or were already known in the art. With respect to the *in situ* hybridization claims in particular, Enzo notes that Abbott's expert admitted that "the practice of the claimed methods would have been enabled with over 50 different probe designs and that deploying those alleged probes in the claimed *in situ* hybridization processes would have yielded predictable results." (D.I. 461 at 5) (internal quotation marks and emphasis omitted) Enzo further contends that the specification's disclosure of probes labeled at non-Ward positions would also have enabled a POSA to practice the *in situ* hybridization claims. (*See id.* at 4; *see also id.* at 3)

At oral argument, Enzo's counsel further argued that the embodiments recited in the liquid phase claims were "irrelevant" because "[t]he novelty of liquid phase hybridization claims lies . . . in the inventive combination of performing liquid phase hybridization with a non-radioactive probe, whatever the structure of the probe, followed by detection." (Tr. at 24-25) As such, in Enzo's view, "the exact nature, structure, location of labeling, sequence, etc. of the non-

radioactive[ly]-labeled probe is tangential to the invention" and, thus, cannot "render the invention [recited in the liquid phase claims] invalid for lack of enablement." (*See id.* at 26-27; *see also id.* at 31-32 (citing '405 patent col. 19 ll. 62-67, col. 20 ll. 2-10, 26-43 as providing support for counsel's argument that "the novelty [of the invention] . . . lies in the use of [a] particular type of hybridization in the liquid phase . . . using non-radioactive labels, followed by detection of those labels"))

In its reply, Abbott argues that Enzo's opposition "repeat[s] arguments that the Court has already rejected" in the Gen-Probe Opinion. (D.I. 462 at 1) (emphasis omitted) Specifically, Abbott notes that even though the Court has already concluded that "no 'part[] of the specification indicates whether an internal phosphate-labeled polynucleotide maintain[s] hybridizability and detectability'" (*id.*) (quoting GP Op. at 15; second alteration in original), Enzo insists that the specification of the '405 patent "'completely' discloses polynucleotides 'labeled at the phosphate moiety'" (*id.*) (quoting D.I. 461 at 1). In Abbott's view, given the lack of disclosure in the specification, a POSA would be required to engage in undue experimentation to identify and determine whether the claimed phosphate-, sugar-, and base-labeled polynucleotides "might be useful in the claimed processes." (*Id.*) Abbott further contends that a POSA would have considered non-Ward-labeled probes to be inoperative, in view of the state of the art at the pertinent time. (*See id.* at 2)[7]

While Enzo contends that the specification discloses the limitations of the asserted claims, Abbott replies that "[t]he '405 patent does not describe the claimed *in situ* hybridization

[7]The Court agrees with Abbott that while inoperability can be a basis for nonenablement, it is not a prerequisite to a finding of nonenablement. (*See* D.I. 462 at 2) (citing *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013))

processes at all" and also fails to "describe[] . . . the conditions (e.g. probe concentration, temperature, salt concentration, etc.) under which the [liquid-phase] process[es] can occur." (*Id.*) (citing testimony of Enzo's expert that liquid-phase hybridization "depends on such conditions") Abbott further asserts that the distinction between the '180 and '405 patent claims "makes no difference" to the Court's analysis: although "the '180 patent claims products [and] the '405 patent claims processes," the claimed processes of the '405 patent "depend on the hybridizability and detectability of the claimed probes." (*Id.*) "Without enabled probes," Abbott argues, "the processes [claimed in the '405 patent] cannot be enabled." (*Id.*; *see also id.* at 1 (arguing that certain probes are not enabled to maintain hybridizability and detectability); Tr. at 9 (counsel for Abbott asserting that "[t]he '405 patent claims are process claims, but this only makes them less enabled, not more"))

"To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.'" *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 188 (Fed. Cir. 2014) (quoting *Wands*, 858 F.2d at 736-37). Having applied this standard to the record evidence, and taking that evidence in the light most favorable to Enzo as the non-moving party, the Court concludes that there is no genuine dispute of fact that the asserted claims of the '405 patent are nonenabled. A reasonable jury could not find for Enzo. Instead, the only conclusion a reasonable jury could reach is that clear and convincing evidence proves the '405 patent is invalid for noneablement.

"[T]he specification must teach those of skill in the art how to make and how to use the invention ***as broadly as it is claimed***." *In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993)

(internal quotation marks omitted; emphasis added). Here, even though the specifications of the '180 and '405 patents are identical in all relevant respects, the asserted claims of the '405 patent are even broader than the asserted claims of the '180 patent that the Court invalidated as nonenabled in the Gen-Probe Opinion. (*See* GP Op.; D.I. 449-1 Ex. 4 at 148-49) Given the breadth of the asserted claims and given the Court's conclusions in the Gen-Probe Opinion, the Court agrees with Abbott that "[a] specification that does not enable the narrower scope of polynucleotides claimed in the '180 patent cannot enable the broader scope of polynucleotides recited in the '405 patent." (D.I. 459 at 1)

Enzo argues that the specification of the '405 patent adequately describes "the broader scope of [non-Ward-labeled] polynucleotides recited in the '405 patent." (*Id.*; *see also* D.I. 461 at 3 (citing parts of specification that describe claimed polynucleotides)) But the Court already rejected this contention in the Gen-Probe Opinion, finding that no "part[] of the specification indicates whether an internal phosphate-labeled polynucleotide maintain[s] hybridizability and detectability." (GP Op. at 15 (internal quotation marks omitted; second alteration in original); *see also Amgen, Inc. v. Genetics Inst., Inc.*, 98 F.3d 1328, 1331 (Fed. Cir. 1996) ("[S]ince the '195 specification did not enable EPO having a specific activity of at least 160,000 IU/AU, enablement of that product could not be relitigated for the identical '837 specification.")) Similarly, with respect to the '405 patent in particular, no part of the specification discloses base labeling at ***all*** non-Ward positions, much less whether all non-Ward base-labeled probes would maintain hybridizability and detectability. (*See* D.I. 459 at 2; *see also Genentech*, 108 F.3d at 1366 ("Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.")). Given the claims' scope

and the specification's limited disclosure, Abbott correctly asserts that a POSA "would have no choice but to make and test a vast number of possible variants to the claimed invention." (D.I. 459 at 2) (internal quotation marks omitted) Undue experimentation would be required, rendering the claims non-enabled.

That the asserted claims are process claims does nothing to reduce the amount of experimentation required. This is because each process in the asserted claims "depend[s] on the hybridizability and detectability of the claimed probes." (D.I. 462 at 2) But since the specification does not enable the claimed probes – no "part[] of the specification indicates whether an internal phosphate-labeled polynucleotide maintain[s] hybridizability and detectability," and no part of the specification discloses base labeling at ***all*** non-Ward positions (GP Op. at 15 (internal quotation marks omitted; second alteration in original); *see also* Tr. at 9 (counsel for Abbott stating that "[i]f the polynucleotide is not enabled at all, . . . the processes using that polynucleotide cannot be enabled")) – the processes recited in the asserted claims of the '405 patent are also non-enabled.

The Court agrees with Abbott's comparison of the present situation to that confronted by the Federal Circuit in *Wyeth v. Abbott Laboratories*, 720 F.3d 1380 (Fed. Cir. 2013). In *Wyeth*, the Federal Circuit affirmed a grant of summary judgment based on nonenablement. *See id.* at 1386. Here, "(1) the claims are far broader than in *Wyeth*,[[8]] (2) the disclosures here are far less

[8]As Abbott argues, "the millions (or more) of [non-Ward]-labeled polynucleotides with varying sequences and lengths covered by each asserted claim of the ['405] patent far exceed the tens of thousands of sirolimus analogs in *Wyeth* and the millions or more of phosphate-labeled polynucleotides covered by the '180 patent." (D.I. 459 at 3) (internal quotation marks omitted; alterations in original)

than in *Wyeth*,[9] (3) the relevant field is even more unpredictable than in *Wyeth*,[10] and (4) the trial-and-error process would have taken even longer than in *Wyeth*."[11] (GP Op. at 15) (internal quotation marks omitted) It follows that here, as in *Wyeth*, there is no genuine dispute that the claims are invalid due to nonenablement.

This same conclusion is supported by consideration of the *Wands* factors. *See* 858 F.2d at 737. Based on the record, a reasonable factfinder could only find: "(1) the quantity of experimentation necessary to arrive at embodiments equal to the full scope of the claims is undue; (2) insufficient direction or guidance is presented in the patent to allow a POSA to avoid undue experimentation; (3) insufficient working examples are present;[12] (4) the invention arises in a field of art that was highly unpredictable at the time of the invention; (5) the prior art showed that the pertinent field was unpredictable; (6) even though the relative skill of those in the art was high, POSAs at the time did not have sufficient knowledge to fill in all that is missing from the patent; (7) the art was, as already noted, highly unpredictable; and (8) the claims are extremely broad." (GP Op. at 16) (internal quotation marks omitted)

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[9]Abbott argues that, "[w]hile the specification in *Wyeth* disclosed at least one working example of the claimed invention (sirolimus) . . . , the ['405] patent discloses none." (D.I. 459 at 3) (internal quotation marks omitted; second alteration in original) Abbott further points out that, "unlike for the '180 patent, Enzo does not even argue that there is a prophetic example showing the labeling chemistry for each non-Ward position." (*Id.*)

[10]Abbott notes that "Enzo's own expert explicitly admitted that, in 1982, there was 'no' 'ab[ility] to predict which chemical transformations and which label types and positions would be likely to work.'" (D.I. 459 at 3) (quoting D.I. 459-1 Ex. 6 at 148)

[11]Abbott contends, "[t]he [trial-and-error] process would have been even longer for the '405 patent than for the '180 patent because the claimed scope of polynucleotides is greater." (D.I. 459 at 3)

[12]Abbott notes that the specification contains no working examples for any non-Ward position. (*See* D.I. 459 at 3)

Enzo opposes this conclusion, arguing that the liquid phase claims are enabled because "the exact nature, structure, location of labeling, sequence, etc. of the non-radioactive[ly]-labeled probe is tangential" to the invention recited in the liquid phase claims. (Tr. at 27) As stated above, however, the processes claimed in the liquid phase claims cannot be enabled if the polynucleotides are not enabled. (*See id.* at 9) Moreover, even if one such process with one particular embodiment were enabled, that would still fail to enable the full scope of the liquid phase claims. This is because a POSA at the pertinent time had "no" "ab[ility] to predict which chemical transformations and which label types and positions would be likely to work," according even to Enzo's expert, Dr. Sherman. (D.I. 459-1 Ex. 6 at 148) Thus, the presence of one enabling embodiment would be insufficient to enable the entire scope of the claim, as of the priority date. *See In re Goodman*, 11 F.3d at 1050 ("[T]he specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed.").

Accordingly, the Court will grant Abbott's motion for summary judgment that the '405 patent is invalid for nonenablement.[13]

[13]The Court is not persuaded by Enzo's citation to *Delaware Display Group LLC v. Vizio, Inc.*, 2017 WL 784988, at *5 (D. Del. Mar. 1, 2017), in which Judge Andrews rejected a nonenablement challenge, reasoning that tangential, non-novel aspects of claims do not require enablement. Here, the record would not permit a reasonable factfinder to find that all of what is nonenabled in the liquid phase claims of the '405 patent is non-novel or tangential to the claimed invention. (*See* D.I. 427 at A2130 ("There was skepticism in the art about non-radioactively labeling a nucleic acid probe at a position other than the Ward positions before June 23, 1982."); *id.* at A2134 (stating that invention claimed in '405 patent "facilitates the use of non-radioactive labels in the hybridization [and] detection process"))

IV. CONCLUSION

For the foregoing reasons, the Court will deny Abbott's motion with respect to the written description requirement and will grant Abbott's motion with respect to nonenablement. An appropriate Order follows.